

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE Docket Number: INFORMATION DISCLOSURE 11128/47602 **STATEMENT** Application Number Filing Date Examiner Art Unit 10/815,362 April 1, 2004 Unassigned 1614 Invention Title Inventors AMORPHOUS SIMVASTATIN CALCIUM AND Ferenc KORODI et al. METHODS FOR THE PREPARATION THEREOF

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandra, VA 22313-1450

## Sir:

- 1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
- 2. In accordance with the Official Gazette of August 5, 2003, which stated that the United States Patent and Trademark Office waived the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. patent applications filed after June 30, 2003, copies of each of the cited U.S. patents and U.S. patent application publications are not being provided.
- 3. Copies of patents, publications or other information listed on the modified PTO Form 1449 are enclosed, unless indicated otherwise.
- 4. A copy of an International Search Report (ISR) recently received in a corresponding PCT application is also enclosed.

5. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due the Commissioner is authorized to charge deposit account number 11-0600 for such fees.

Respectfully submitted,

Date: 10/19/04

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Subtitute for form 1449A/PTO

 Sheet
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 Attorney Docket Number
 11128/47602

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No.¹	Document Number	- Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevan	
		Number - Kind Code <sup>2</sup> (if known)			Passages or Relevant Figures Appear	
		US- 6,797,831 B2	September 28, 2004	Dandala et al.		
		US- 4,820,850	April 11, 1989	Verhoeven et al.		
		US- 2002/0115712 A1	August 22, 2002	Szabo et al.		
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FOREIGN PATENT DOCUMENTS						
Examin er Initials*		Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	Cite No. <sup>1</sup>	Country Code <sup>3</sup> – Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY			
		EP 0 864 560 A1	September 16, 1998	Khanna et al.		
		EP 511 867 A1	November 4, 1992	Dabora et al.		
		WO 02/20457 A1	March 14, 2002	Tillyer et al.		
		WO 03/018570 A1	March 6, 2003	Lee et al.		
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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
		Hancock et al. "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems"  J. Pharmaceutical Sciences, Vol. 86, No. 1, p. 1-12, (1997)			

Examiner Signature	Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.